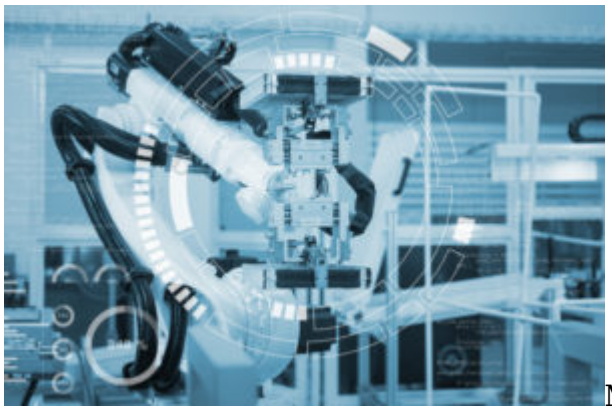
Medtech M&A and VC Signal Positive Momentum Entering 2025


Medtech mergers and acquisitions (M&A) and venture capital (VC) showed signs of life in 2024, contributing to an overall optimistic outlook for the sector this year despite lingering headwinds.

Strategic investments are expected to continue as medtech companies innovate, particularly in areas such as AI-driven diagnostics, wearables and remote monitoring devices, and advanced surgical technologies.

Private, venture-backed M&A activity for medical devices—which picked up in the second half of last year and started 2025 strong with two ten-digit acquisitions and two spin-offs by strategics—could continue rising amid a more deregulatory backdrop under the new presidential administration.

Still, challenges persist that could slow growth. Early-stage VC deals in the sector have faced difficulties, and private M&A exit timelines have increased. Uncertainty regarding the path of interest rates and the broader economy also muddy the outlook.

Read the full insight **here**.

Modernizing the FDA’s 510(k) Program for Medical Devices: Selection of Predicate Devices and Use of Clinical Data in 510(k) Submissions

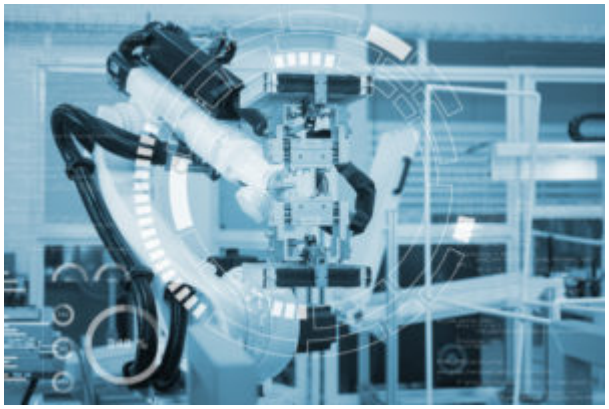
On September 6, 2023, the US Food and Drug Administration (FDA) released a trio of draft guidances in its efforts to "strengthen and modernize" the 510(k) Program and provide for more "predictability, consistency, and transparency" for the 510(k) premarket review process. In this post, we discuss the two new draft guidances with broad applicability to the 510(k) Program:

- "**Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission**"
- "**Recommendations for the Use of Clinical Data in Premarket Notification [510(k)] Submissions**"

The two draft guidances address a number of fundamental issues of concern with the 510(k) process.

Read the full client alert **here**.

The MHRA Proposes to Extend the Period of Acceptance of CE Marked Medical Devices in Great Britain Beyond 30 June 2023



BACKGROUND

On 28 April 2023, the UK's medical devices regulator, the Medicines & Healthcare products

Regulatory Agency (MHRA), announced its intention to extend the acceptance of CE marked medical devices in Great Britain (England, Scotland and Wales) beyond 30 June 2023.

Following the UK's departure from the EU, CE marked medical devices can currently be placed on the Great Britain market under the existing transitional arrangements until 30 June 2023. The proposed extension will support the ongoing safe supply of medical devices to Great Britain and ease the transition to the future regulatory framework for medical devices.

The government intends to introduce regulations in the future that will implement a substantial reform of the current regulatory framework for medical devices in the UK and is now aiming for core aspects of the UK's future regime for medical devices to apply from 1 July 2025.

PROPOSED EXTENSION TO TRANSITIONAL ARRANGEMENTS

The UK Medical Device Regulations 2002 (UK MDR) currently provide that the acceptance of CE marked medical devices on the Great Britain market will end on 30 June 2023. However, the MHRA intends to introduce legislation before 30 June 2023 which will provide that CE marked medical devices may be placed on the Great Britain market to the following timelines:

- General medical devices compliant with the EU medical devices directive (EU MDD) or EU active implantable medical devices directive (EU AIMDD) with a valid declaration and CE mark can be placed on the Great Britain market up until the sooner of (i) the expiry of the CE mark certificate or (ii) **30 June 2028**;
- In vitro diagnostic medical devices (IVDs) compliant with the EU in vitro diagnostic medical devices directive (EU IVDD) can be placed on the Great Britain market up until the sooner of (i) the expiry of the CE mark certificate or (ii) **30 June 2030**; and
- General medical devices, including custom-made devices, compliant with the EU medical devices regulation (EU MDR) and IVDs compliant with the EU in vitro diagnostic medical devices regulation (EU IVDR) can be placed on the Great Britain market up until **30 June 2030**.

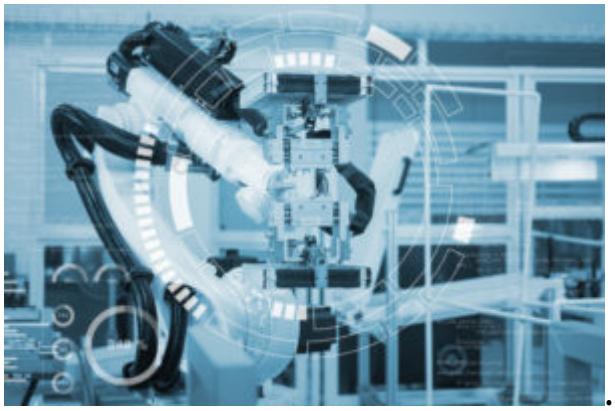
The above extensions will not include class I medical devices and general IVDs (for which the conformity assessment under EU MDD or EU IVDD did not involve a notified body), which can only be placed on the Great Britain market if the involvement of a notified body would be required under the EU MDR or IVDR (i.e., if it is an up-classified device or a reusable surgical instrument Class I device). Similarly, the extensions will not include custom-made devices that are compliant with the EU MDD or EU AIMDD, which can no longer be placed on the Great Britain market.

WHAT HAPPENS NEXT?

The legislation to implement the proposed extension will now be considered by the UK Parliament, and final approval is expected before 30 June 2023.

The European Commission Proposes to Extend the Transition Deadline in the EU

Medical Device Regulation

**... a major change to the Regulation is needed to prevent shortages of life-saving medical devices...**

Background

On Friday 9 December 2022, the European Commission proposed to extend the transition deadline in the **Medical Device Regulation (EU) 2017/745** (**MDR**). According to the European Commissioner for Health and Food Safety, Stella Kyriakides, a major change to the Regulation is needed to prevent shortages of life-saving medical devices, from implants and prosthetics to ventilators and pacemakers.

Medical devices in the EU are regulated under the MDR, and the MDR replaced the previous Medical Devices Directive 93/42/EEC (**MDD**) and the Active Implantable Medical Devices Directive 90/385/EEC (**AIMDD**) on 26 May 2021. Currently, medical devices can be placed on the EU market under a CE mark certificate issued under the MDD or AIMDD until 26 May 2024 (**Transition Deadline**). After the Transition Deadline, these products will require a CE mark certificate issued under the MDR so that they remain available on the EU market – a potentially costly and time-consuming process.

A broad range of stakeholders in the medtech sector consider the Transition Deadline to be unattainable. The pandemic, shortages of raw materials caused by the conflict in Ukraine and low Notified Body capacity have collectively put a strain on the ability for medical device manufacturers to meet the Transition Deadline. Without an extension to the Transition Deadline, it is anticipated that a significant number of medical device manufacturers would need to take their products off the EU market due to an inability to comply with the new requirements under the MDR within the required timeline.

Key Proposals

The European Commission has proposed the following legislative amendments:

- Extension of the Transition Deadline in the MDR based on the risk class of each device:
  - 26 May 2027 for Class III and Class IIb medical devices; and
  - 26 May 2028 for Class IIa and Class I medical devices.
- Extension of the validity of CE mark certificates issued under the MDD and AIMDD if needed for legal and practical reasons (e.g. to access markets outside of the EU that accept products with a CE mark), provided that:
  - the device does not present an unacceptable risk to health and safety;
  - the device has not undergone significant changes in design or intended purpose; and

    - the manufacturer has already undertaken the necessary steps to launch the CE mark certification process under the MDR (e.g. lodged an MDR application with a Notified Body by 26 May 2024).
- Elimination of the "sell-off" date under the MDR and under the **In Vitro Diagnostic Medical Device Regulation (EU) 2017/746** (**IVDR**) to avoid safe medical devices and in vitro diagnostics (e.g. blood glucose meters) that are already on the EU market from having to be discarded by 27 May 2025.

Next Steps

The European Commission intends to provide these legislative amendments to the EU legislature for consideration at the beginning of 2023.

The European Commission also intends to undertake a comprehensive evaluation of the MDR by May 2027. The purpose of the evaluation is to identify structural problems with the MDR and potential medium and long-term solutions to these concerns.

As a final note, except for the elimination of the "sell-off" date, none of the proposed legislative amendments applies to in vitro diagnostics. Given that there are still few Notified Bodies under the IVDR, similar amendments might also be required for in vitro diagnostics in the near future.

Congress Expands Pathway for Drug & Device Manufacturers' Pre-Approval Communication of Health Care Economic Information to Payors, Formularies, & Similar Entities



The legislation previously introduced as the **Pre-Approval Information Exchange Act of 2022** ("PIE Act") was passed as part of Congress's December 23, 2022 omnibus spending bill. Once signed into law, this legislation will amend the Federal Food, Drug, and Cosmetic Act's (FDCA's) provisions on misbranded drugs and devices to formally allow drug and medical device manufacturers to proactively share investigational drug and device information, including health care economic information, with payors, health plans, formulary committees, and other similar entities *prior* to the clearance or approval of the drug or device or new use of the drug or device but

with now-statutory strings attached.

The US Food and Drug Administration (FDA) has long had the authority to enforce against pre-approval *promotional* communications, and a pathway for pre-approval communication of health care economic information regarding the selection of drugs for coverage and reimbursement was enacted under the Food and Drug Administration Modernization Act of 1997. **Current guidance from FDA**, finalized in 2018, expressly permits drug and device companies to provide some details about investigational products or investigational uses of marketed products to payors, formulary committees, and similar entities prior to approval or clearance of the product or its new use; however, for device companies this has come in the form of non-binding guidance that lacks a formal anchor in the statutory language. The inclusion of the legislation previously known as the PIE Act in the omnibus spending bill formally establishes a statutory pathway built on FDA's 2018 final guidance for both drug and medical device companies to engage in pre-market communications about health care economic information with payors, formulary committees, and similar entities.

Read the client alert **here**.

Avoiding Misbranding: Words Matter When Describing the Regulatory Status of 510(k) Cleared Devices and Registered Device Establishments

When it comes to discussing medical devices regulated by the U.S. Food and Drug Administration (FDA), words such as "approved" and "cleared" cannot be used interchangeably as these terms carry a particular meaning. Similarly, creating an impression of approval of a device establishment or its devices because the establishment is registered with FDA also is prohibited. Long-standing regulatory provisions, **21 C.F.R. § 807.97** and **21 C.F.R. § 807.39**, set forth, respectively, the FDA's position that approval and clearance are not interchangeable and that device establishment registration does not denote approval of the establishment or its devices. Importantly, these provisions also highlight the consequences to industry for misusing terms when discussing the regulatory status of a device or a device establishment.

When seeking to market a new device for which a premarket notification must be submitted to the FDA demonstrating that the device to be marketed is substantially equivalent to a legally marketed device, the submitter must obtain an order of substantial equivalence from the FDA, which is

commonly referred to as a 510(k) *clearance*. Conversely, to market a new device for which a premarket approval application must be submitted to the FDA, the applicant must obtain FDA's *approval* of the application. While FDA review and FDA action occur for both types of medical devices, the outcomes of clearance and approval are distinctly different and carry legal consequences. Specifically, 21 C.F.R. § 807.97 states that "[a]ny representation that creates an impression of official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding." Additionally, 21 C.F.R. § 807.39 states that "[a]ny representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding."

We researched Warning Letters in **FDA's Warning Letter Database** and found that FDA issued four Warning Letters citing violations of § 807.97 since 2017 and thirteen Warning Letters citing violations of § 807.39 since 2017.

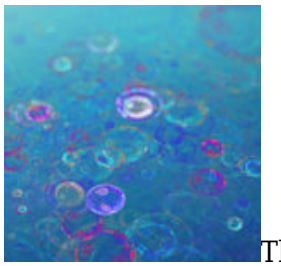
Many of the representations that FDA found to be misleading under § 807.97 were straightforward violations, such as language on product websites stating that cleared devices are "FDA approved," or listings of device clearances under the heading "FDA Approvals." In one instance, FDA found the website to be misleading under both § 807.39 and § 807.97 because the company claimed the device had been cleared by the FDA, when in fact it was marketing a 510(k) exempt device for an indication that would require a de novo authorization which the company had not obtained, and the website claimed the company maintained an active listing, which was hyperlinked to the company's FDA Establishment Registration and Device Listing for only the 510(k) exempt device.

In response to the COVID-19 public health emergency, FDA issued twelve Warning Letters related to representations regarding masks and antibody tests that were found to be misleading under § 807.39. In virtually all of these instances, company websites displayed unofficial "certificates of FDA registration" issued by third parties which claimed to certify that the manufacturer had completed FDA Establishment Registration and Device Listing. These certificates often incorporated unauthorized reproductions of FDA's logo and motifs of the U.S. flag, giving the impression of official government documents. FDA consistently found the display of these certificates to be misleading, even when they included ostensible "disclaimer" language stating that the certificates did not denote FDA endorsement or approval. FDA repeatedly found that these disclaimers did not adequately limit or otherwise mitigate the misleading impression of the certificates because they were phrased, designed, and placed in a manner where they could be easily overlooked.

These Warning Letters present a cautionary tale to all sponsors intending to market new medical devices. While sponsors may be tempted to claim their devices are approved by the FDA following the agency's review of a premarket notification or upon completion of FDA Establishment Registration and Device Listing, § 807.97 and § 807.39 make clear that such claims will constitute misbranding. Sponsors can avoid § 807.97- and § 807.39-related Warning Letters and associated liability by carefully reviewing all of the language on their marketing materials and websites to ensure that none of their representations create the impression of official approval based on reference to a premarket notification submission or establishment registration.

Visit the **Goodwin on Medtech hub** to stay informed on important developments affecting medtech innovators and investors.

FDA Announces Total Product Life Cycle Advisory Program (TAP) Pilot

The U.S. Food and Drug Administration's ("FDA" or "the Agency") Center for Devices and Radiological Health ("CDRH") recently announced the launch of its Total Product Life Cycle Advisory Program ("TAP") Pilot. The first phase of this voluntary initiative, called TAP Pilot Soft Launch, will be conducted during fiscal year ("FY") 2023 with enrollment beginning on January 1, 2023.

The Agency committed to establishing the TAP Pilot as part of the MDUFA V reauthorization, and the Agency's long-term vision for TAP is "to help spur more rapid development and more rapid and widespread patient access to safe, effective, high-quality medical devices of public health importance." As part of the TAP Pilot, the FDA will provide strategic engagement for such devices by:

- Improving participants' experiences with the FDA by providing for more timely premarket interactions
- Enhancing the experience of all participants throughout the device development and review process, including FDA staff
- Facilitating improved strategic decision-making during device development, including earlier identification, assessment, and mitigation of device development risk
- Facilitating regular and solutions-focused engagement early in device development between FDA review teams, participants, and other stakeholders, such as patients, providers, and payers
- Collaborating to better align expectations regarding evidence generation, improve submission quality, and improve the efficiency of the premarket review process

Read client alert **here**.

FDA Issues Final Clinical Decision Support Software Guidance

On September 28, 2022, the U.S. Food and Drug Administration ("FDA" or "the Agency") issued its long-awaited final guidance, "Clinical Decision Support Software" (the "CDS Guidance"). The CDS Guidance follows the Agency's September 2019 draft guidance of the same name (the "Draft Guidance") and seeks to clarify several key concepts for determining whether clinical decision support ("CDS") software is a medical device.

Specifically, the CDS Guidance provides the Agency's interpretation of the four criteria established by the 21st Century Cures Act for determining whether a decision support software function is excluded from the definition of a device (i.e., is considered "Non-Device CDS"). A software function must meet all of the following four criteria to be considered Non-Device CDS:

1. Not intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device ("IVD") or a pattern or signal from a signal acquisition system
2. Intended for the purpose of displaying, analyzing, or printing medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines);
3. Intended for the purpose of supporting or providing recommendations to a health care professional ("HCP") about prevention, diagnosis, or treatment of a disease or condition
4. Intended for the purpose of enabling such HCP to independently review the basis for the recommendations that such software presents so that it is not the intent that the HCP rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient

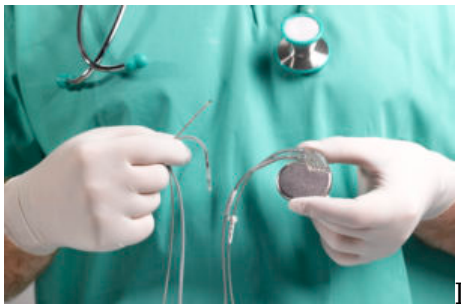
Software functions that *do not* meet all four criteria are considered device functions subject to FDA oversight. Notable updates to FDA's interpretation of the four criteria include the following.

Read the Goodwin insight **here**.

Visit the **Goodwin on Medtech hub** to stay informed on important developments affecting medtech innovators and investors.

Planning For The End: Goodwin FDA attorneys Steve Tjoe and Susan Lee highlight key takeaways From FDA's draft guidances proposing transition plans for medical devices marketed under EUAs or

enforcement policies during the COVID-19 Public Health Emergency

During the COVID-19 public health emergency, the United States Food and Drug Administration (FDA) has issued hundreds of Emergency Use Authorizations (EUAs) and numerous enforcement policies to facilitate the availability of important medical devices. On December 23, 2021, FDA published two draft guidances setting forth the Agency's proposed process for transitioning the multitude of devices brought to market under these circumstances to full compliance with FDA requirements:

- Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (the "EUA Transition Draft Guidance"); and
- Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (the "Enforcement Policies Transition Draft Guidance").

In our **recent Alert**, we summarize some key takeaways from FDA's proposed transition plan for manufacturers of devices marketed under a COVID-19 EUA ("EUA Devices") and devices marketed under one of more than 15 COVID-19 enforcement policies listed in the guidance ("Enforcement Policy Devices"). **Read More**

---

3 Key Considerations for Promoting Transparency for AI/ML-Enabled Medical Devices



Today, developers of innovative medical devices are increasingly utilizing artificial intelligence (AI)

and machine learning (ML) technologies to derive important insights with the promise of transforming the delivery of healthcare. Yet, concerns regarding the transparency of AI/ML-enabled devices, or the degree to which information about such devices is communicated to stakeholders, threatens not only perceptions as to the safety and effectiveness of such devices by regulators, but also trust in such technologies from patients and healthcare providers alike.

Read the full **article** written by **Steven Tjoe** in *PM360 Magazine*.

Visit the **Goodwin on Medtech hub** to stay informed on important developments affecting medtech innovators and investors.